# PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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# PCT

## WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

(PCT Rule 66)

| | |
|---|---|
| Date of mailing *(day/month/year)* | 09.06.2005 |
| Applicant's or agent's file reference: 03/111/EST | **REPLY DUE** **within 2 month(s)** from the above date of mailing |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/IT 03/00419 | 03.07.2003 | 03.07.2003 |

International Patent Classification (IPC) or both national classification and IPC
A61K7/16

Applicant
BETAFARMA S.P.A. et al.

1. ☒ The written opinion established by the International Searching Authority:
   ☒ is ☐ is not
   considered to be a written opinion of the International Preliminary Examining Authority
2. This second report contains indications relating to the following items:
   - ☒ Box No. I Basis of the opinion
   - ☐ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

   **When?** See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).
   **How?** By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.
   **Also:** For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4*bis*. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.
   **If no reply is filed,** the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 03.11.2005

| Name and mailing address of the international preliminary examining authority: | Authorized Officer |
|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Sala-Jung, N<br>Telephone No. +49 89 2399-6050 |

**WRITTEN OPINION OF THE INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY**

International application No.
PCT/IT 03/00419

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This opinion is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this opinion is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

   **Description, Pages**

   1-4 as originally filed

   **Claims, Numbers**

   1-8 filed with telefax on 15.07.2004

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 3,4

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 3,4 are so unclear that no meaningful opinion could be formed *(specify)*:

**see separate sheet**

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search opinion has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

| | | |
|---|---|---|
| the written form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |
| the computer readable form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See supplemental sheet for further details

**Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | |
| | No: | Claims | 1,2,5-8 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1,2,5-8 |
| Industrial applicability (IA) | Yes: | Claims | 1,2,5-8 |
| | No: | Claims | |

2. Citations and explanations:

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Dependent claim 3 seems to have been miswritten. Therefore this claim does not relate to a clearly defined subject-matter. Claim 4 is directly dependent from claim 3 and is therefore also not clear.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**V-1.** Reference is made to the following documents:

D1: DATABASE CAPLUS [Online] XP002271164 retrieved from STN Database accession no. 1995:453547

D2: WO 96/15770 A (WARNER LAMBERT CO) 30 May 1996 (1996-05-30)

D3: US-A-5 294 431 (AFFLITTO JOHN ET AL) 15 March 1994 (1994-03-15)

D4: EP-A-0 244 363 (WARNER LAMBERT CO) 4 November 1987 (1987-11-04)

D5: US-A-5 401 496 (FITZIG SIMON ET AL) 28 March 1995 (1995-03-28)

D6: WO 99/22703 A (LURIYA LEONID ; LURIDENT LTD (IL); LURIYA ELENA (IL)) 14 May 1999 (1999-05-14)

D7: EP-A-0 528 457 (UNILEVER PLC ; UNILEVER NV (NL)) 24 February 1993 (1993-02-24)

D8: US-A-5 416 075 (AU VAN ET AL) 16 May 1995 (1995-05-16)

**V-2.** Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 2, 5 to 8 is not new in the sense of Article 33(2) PCT.

The document D1 discloses a gargle which just prior to use comprises:
an oil phase (polyethylene glycol, polyoxyethylene hydrogenated castor oil) containing antibacteric substances (1-menthol, eucalyptus oil),
and an aqueous phase containing antibacteric substances (cetylpyridinium chloride, ethyl alcohol).

The subject-matter of claims 1, 5, 7 and 8 is therefore anticipated by D1, although a film on the user teeth is not described in D1 (PCT Guidelines 5.21).

The document D2 (ex.I) discloses an antimicrobial mouthwash containing an oil phase containing antibacteric substances (peppermint oil, methyl salicylate, thymol, menthol) and an aqueous phase containing antibacteric substances (cetylpyridinium chloride, ethyl alcohol).
The subject-matter of claims 1, 2, 7 and 8 is therefore anticipated by D2 (PCT Guidelines 5.21).

The document D3 (ex.1 C&D) discloses antimicrobial mouthrinses comprising an oil (flavoring oil) and a water-insoluble non cationic antibacterial agent (col.2, l.34-40) (triclosan), water and ethanol as water soluble antibacteric substance. D3 (ex.2 C) also discloses a liquid dentifrice comprising a flavoring oil, triclosan, water and ethyl alcohol.
The subject-matter of claims 1, 2, 6 to 8 is therefore anticipated by D3 (PCT Guidelines 5.21).

The document D4 (ex.4) discloses an antimicrobial mouthrinse comprising an oil phase containing water-insoluble antibacteric substances (thymol, eucalyptol, methyl salicylate, menthol), water, and water soluble antibacteric substances (ethanol, chlorhexidine digluconate).
The subject-matter of claims 1, 2, 6 to 8 is therefore anticipated by D4 (PCT Guidelines 5.21).

The document D5 (ex.2,6) discloses an antimicrobial mouthwash containing an oil phase (ESTOL 3604, refined cod liver oil) containing an antibacteric substance (menthol) and an aqueous phase containing a water soluble antibacteric substance (hexadecyltrimethylammonium chloride or chlorhexidine digluconate). The oil displaces bacterial plaque from the teeth surface (col.1, l.35-50), which means implicitely that an oil film covers the teeth.
The subject-matter of claims 1, 2, 5 to 8 is therefore anticipated by D5.

The document D6 (ex.5,6) discloses antimicrobial mouthwash formulations

containing: ex.5: an oil phase containing an antibacteric substance (menthol) and an aqueous phase containing water soluble antibacteric substances (chlorhexidine diacetate, ethanol), ex.6: an oil phase containing antibacteric substances (triclosan, menthol) and an aqueous phase containing a water soluble antibacteric substance (ethanol). The lipid carrier has a high adhesiveness to the oral tissues (p.3, l.7- p.4, l.11).
The subject-matter of claims 1, 6 to 8 is therefore anticipated by D6 (PCT Guidelines 5.21).

**V-3.** Inventive step
As none of claims 1, 2 and 5 to 8 is new, no inventive step can be discussed. It is nevertheless noted that documents D5 to D8 would be relevant if new claims were filed.

Re: International Application No. PCT/IT03/00419
filed on 03/07/2003 in the name of
BETAFARMA S.P.A. et al.

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Sir,

This is in response to the PCT Written Opinion (PCT Rule 66) mailed on 09/06/2005.

The observations of the Examiner have been carefully considered.

Claims 1 to 8 have been cancelled and new claims 1 to 6 have been submitted in order to clearly distinguishing Applicant's invention over the prior art documents D1 to D8, either individually or in combination.

From the new main claim, which is substantially a combination of previous claims 1, 2 and 5, the gist of the invention should be envisaged in the fact that Applicant's antibacteric composition comprises, dissolved in said oil phase, antiseptic substances exclusively soluble in said oil phase and, dissolved in said aqueous phase, water soluble antibacteric substances, in that said aqueous phase varies from about 60% w/w to about 95% w/w, that said oil phase

varies from about 5% w/w to about 40% w/w, thereby said composition forms on a user teeth an oil film resisting against water rinsings.

It is believed that such a new main claim is actually novel and non obvious over the prior art documents. In fact none of the prior art documents teaches an actibacteric composition in which in the oil phase are dissolved antiseptic substances which are exclusively soluble in said oil phase, that in said aqueous phase are dissolved water soluble antibacteric substances, and that the rate of the aqueous phase and the oil phase has the values shown in the main claim. Moreover, none of the prior documents discloses the most important feature of the invention, that is that Applicant's antibacteric composition forms on the user teeth an oil film resisting against water rinsings. In this connection Applicant desires to draw the attention of the Examiner that the document D1, as admitted by the Examiner, does not form any film on the user teeth; this same observation is also true for the document D2, the document D3, the document D4.

With respect to the document D5, Applicant does not agree with the assertion of the Examiner that "the oil displaces bacterial plaque from the teeth surface, which means implicitly that an oil film cover the teeth". This fact is not true: actually, the document US-A-5 401 496 (D5) teaches, on column 1, lines 35 to 50, that the synthetic oil acts to separate the mentioned bacterial plaque by mechanical shear action during the operations of rinsing (in the case of mouthwashes), toothbrush friction (in the case of pastes, creams or gels) and chewing (in the case of masticables). This does not means that a protective

film is formed on the teeth, in fact, this prior preparation operates via two different and simultaneous processes: 1) by desorption and displacement of bacteria and other types of microorganisms adhering to the teeth surface and other sectors of oral cavity and (2) by absorption and subsequent displacement of the substances segregated by the mentioned microorganisms which are the immediate originators of the oral halitosis. No film disclosed or suggested, as stated, in this prior document. Moreover, this prior document composition comprises an oil phase including a synthetic oil of caprilic acid or triglyceride mixture in a concentration effective to mechanically shear, separate, desorb and/or displace oral halitosis, originating bacteria and/or bacteria plaque adhering to teeth and to oral cavity gums: this oil phase, in other words provides to generate a mechanically shear, separate, desorb and/or displace function and not to form any film on the teeth. Finally, no rates of the aqueous phase or oil phase are indicated in this prior document, as well as in any of the other prior documents. By resuming, none of the prior document cited by the Examiner neither discloses not suggests that composition, having the specific rates taught in the main claim, is adapted to form on the teeth a protective film.

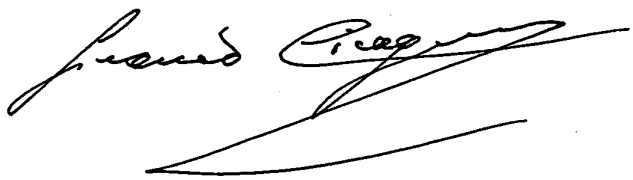
Accordingly, and as sated, it is respectfully believed that new claim should have patentable merits over the prior art documents together with the other dependent claims.

With respect to new claim 2, corresponding to previous claim 3, Applicant does not comprise the observation

of the Examiner that it seems to have been miswritten: actually claim 2 (corresponding to previous claim 3) is fully supported by the disclosure, as well as new claim 3 (corresponding to previous claim 4). In particular, claims 3 and 4 disclose antibacteric substances including moistening agents which are neither disclosed nor suggested by any of the prior art documents.

In view of the foregoing discussion Applicant respectfully submits that new claims provide an inventive antibacteric composition.

Respectfully submitted



Encl.: New claim 1 to 6 pages 5 and 6

## CLAIMS

1. A mouthwash antibacteric composition for sanitizing the buccal cavity, said antibacteric composition comprising an oil phase and an aqueous phase, characterized in that said composition further comprises, dissolved in said oil phase, antiseptic substances exclusively soluble in said oil phase, and, dissolved in said aqueous phase, water soluble antibacteric substances, in that said aqueous phase varies from about 60% w/w to about 95% w/w, that said oil phase varies from about 5% w/w to about 40% w/w, thereby said composition forms on a user teeth an oil film resisting agsinst water rinsings.

2. A composition, according to claim 1, characterized in that said water soluble antibacteric substances comprise moistening agents, alcohols, fluorinated salts, sweetening substances, coloring substances, pH adjusters and so on.

3. A composition, according to claim 2, characterized in that said moistening substances are selected from glycerol, sorbitol, xylitol, glycoles, said alcohols being selected from ethyl alcohol and propyl alcohol and said sweetening substances being selected from saccharine and aspartames.

4. A composition, according to claim 1, characterized in that said oil phase comprises vegetable oils, mineral oils, aliphatic esters, aliphatic ethers, aliphatic alcohols, triglycerides and aliphatic hydrocarbons.

5. A composition, according to claim 1, characterized in that said oil phase comprises

aromatizing oils.

6. A composition, according to one or more of the preceding claims, characterized in that said composition further comprises an emulsifying system of an oil in water (O/W) type, adapted to form stable emulsions.